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Registration Decision

Beauveria bassiana strain GHA

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Registration Decision for *Beauveria bassiana* strain GHA

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Beauveria bassiana* Technical, Botanigard ES and Botanigard 22 WP, containing the technical grade active ingredient *Beauveria bassiana* strain GHA, to control whitefly, aphids and thrips in greenhouse ornamentals and vegetables.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2009-03, *Beauveria bassiana* strain GHA. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Beauveria bassiana* strain GHA and summarizes the Agency's decision, the reasons for it and provides a summary of comments received during the consultation process as well as PMRA's response to these comments (see Appendix I). This decision is consistent with the proposed registration decision stated in PRD2009-03.

For more details on the information presented in this Registration Decision, please refer to the PRD2009-03 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's *(a)* efficacy; *(b)* effect on host organisms in connection with which it is intended to be used; and *(c)* health, safety and environmental benefits and social and economic impact".

most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Beauveria bassiana* strain GHA?

Beauveria bassiana strain GHA is a microbial pest control agent in the end-use products, Botanigard ES and Botanigard 22 WP. These end-use products provide control of whitefly, aphids, and thrips on greenhouse ornamentals and vegetables.

Beauveria bassiana is a fungus that grows naturally in soils throughout the world and acts as a parasite on various insect species. *Beauveria bassiana* is a "generalist entomopathogenic fungi", which is a fungus which causes a disease in many types of insects. In the case of *Beauveria bassiana,* it causes a disease called "white muscardine disease" in most insects. While insects living in or near the soil have evolved natural defences against this fungus as it is common in their natural environment, it can be used as a biological insecticide against most other insects.

Health Considerations

Can Approved Uses of *Beauveria bassiana* strain GHA Affect Human Health?

Beauveria bassiana strain GHA is unlikely to affect human health when used according to the label directions

People could be exposed to *Beauveria bassiana* strain GHA when handling and applying the products. The PMRA considers several key factors when assessing health risks: the microorganism's biological properties (for example, production of toxic byproducts), reports of any adverse incidents, its potential for pathogenicity, infectivity and toxicity as determined in toxicological studies as well as the likely levels to which people may be exposed to this strain relative to exposures already encountered in nature to other strains of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in the hopes of identifying any potential pathogenicity, infectivity and toxicity concerns. *Beauveria bassiana* Technical was found to be a mild eye irritant. Therefore, the product labels will have the appropriate label statements.

No other significant toxicity or signs of disease were observed when *Beauveria bassiana* strain GHA was tested on laboratory animals.

Residues in Water and Food

Dietary risks from food and water are not of concern

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limits (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Strains of *Beauveria bassiana* are common in nature and the use of Botanigard ES and Botanigard 22 WP in greenhouses is not expected to significantly increase natural environmental background levels of this microorganism. Furthermore, no significant adverse effects were reported when *Beauveria bassiana* strain GHA was administered orally to rats. Therefore, the establishment of an MRL is not required for *Beauveria bassiana* strain GHA. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risks are minimal to non-existent.

Occupational Risks From Handling Botanigard ES and Botanigard 22 WP

Occupational risks are not of concern when Botanigard ES and Botanigard 22 WP are used according to label directions, which include protective measures.

Workers using Botanigard ES and Botanigard 22 WP can come into direct contact with *Beauveria bassiana* strain GHA on the skin, in the eyes, or by inhalation. For this reason, the label will specify that workers using Botanigard ES and Botanigard 22 WP must wear gloves, long-sleeved shirts, long pants, a NIOSH approved respirator (with any N, P, R or HE filter), and shoes plus socks. Eye goggles are also required when handling Botanigard 22WP. Early-entry workers will also be restricted from entering areas where Botanigard ES and Botanigard 22 WP have been applied for a period of 12 hours unless wearing the indicated personal protective equipment.

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Beauveria bassiana* strain GHA is Introduced into the Environment?

Environmental risks are not of concern

Information on the environmental fate of *Beauveria bassiana* strain GHA suggests that, as a common soil microorganism, it is likely that *Beauveria bassiana* strain GHA could survive in outdoor soil under favourable environmental conditions (i.e., moisture, acidity levels) but that over time the populations of *Beauveria bassiana* strain GHA would return to natural background levels.

The effects of *Beauveria bassiana* strain GHA on birds, earthworms, fish, aquatic arthropods, terrestrial and aquatic plants, and beneficial and/or environmentally-important insects were examined. Although the risk to non-target organisms was found to be acceptable, in order to be protective of beneficial insects (including bees), the end-use product labels will instruct users to minimize overspray in the greenhouse. Labelling will also advise users that Botanigard ES and Botanigard 22WP may be harmful to bees exposed by direct contact, and will instruct users to avoid applying the products to areas where honeybees are actively foraging. To reduce the potential for phytotoxic effects on crop plants, advisory statements notifying users to spot test plant surfaces before applying product for the first time and to minimize the accumulation of visible residues on plant surfaces, will also be required on the end-use product labels under the directions for use section.

Although avian pulmonary/inhalation/injection, wild mammal, and microorganism testing were not conducted, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected.

Value Considerations

What Is the Value of Botanigard ES and Botanigard 22 WP?

Botanigard ES and Botanigard 22 WP are biopesticides that can be used to control whiteflies, aphids, and thrips on greenhouse vegetables and ornamentals.

These are biological control products which may be used on greenhouse ornamentals and vegetables in place of conventional chemical insecticides. The data reviewed demonstrated that Botanigard ES and Botanigard 22 WP will generally provide acceptable control of whiteflies, aphids, and thrips on greenhouse vegetables and ornamentals. However, depending on humidity and temperature, efficacy can be variable. Under unfavourable conditions, these products may not always provide good control. This is not unexpected given the mode of action of these products (a fungal biological control agent which causes a disease).

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures being proposed on the labels of Botanigard ES and Botanigard 22 WP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health
Due to concerns with users developing allergic reactions through repeated high exposure to *Beauveria bassiana* strain GHA, anyone handling or applying Botanigard ES or Botanigard 22 WP must wear waterproof gloves, a long-sleeved shirt, long pants, and shoes plus socks. In addition, mixers/loaders and applicators must wear a dust/mist filtering mask. Furthermore, anyone handling or applying Botanigard 22 WP will be required to wear eye goggles as this formulation is a moderate eye irritant.

Environment
As a general precaution, the label prohibits the direct application of the products to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), estuaries or marine habitats. The label also directs handlers to not contaminate surface water by disposal of equipment wash waters.

In order to be protective of beneficial insects (including bees) users will be instructed to minimize overspray in the greenhouse. Labelling will also advise the user that Botanigard ES and Botanigard 22 WP may be harmful to bees exposed by direct contact, and will instruct users to avoid applying the products to areas where honeybees are actively foraging.

As some strains of *Beauveria bassiana* have been shown to be toxic to honeybees, users are directed to avoid applying the products to areas where honeybees are actively foraging.

To reduce the potential for phytotoxic effects on crop plants, advisory statements notifying users to spot test plant surfaces before applying product for the first time and to minimize the accumulation of visible residues on plant surfaces, are required on the label under the directions for use section.

One of the formulants in Botanigard ES contains heavy aromatic petroleum distillates which are toxic to aquatic organisms and will therefore be labelled as such on the end-use product label.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

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5 As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comments on precautionary statements proposed for the product label

A comment was received regarding the need for clarification of labels statements with respect to non-target organisms.

Response

PMRA is in agreement with the information provided in the comment.

The "Environmental Considerations" section of this document reflects the comment.

The comment also impacts the text of Section 4.2.1 and Section 7.3 of the Proposed Registration Decision PRD2009-03, *Beauveria bassiana* strain GHA.

The amended sections are presented below:

4.2.1 Effects on Terrestrial Organisms (Paragraph 16)

As the proposed uses of Botanigard ES and Botanigard 22 WP are limited to greenhouses there is no direct exposure to outdoor environments, and outside environments are only expected to be exposed to *Beauveria bassiana* strain GHA through operational activity (for example, removal and composting of spent crop growing media). Once outside, the dispersal of *Beauveria bassiana* strain GHA should be limited to mostly runoff and vectors. Based on these considerations, the amount of *Beauveria bassiana* strain GHA transferring to outdoor environments is expected to be low. Consequently, a significant increase in natural populations of *Beauveria bassiana* in outdoor terrestrial environments is not expected, and therefore hazards to non-target terrestrial organisms are expected to be minimal to non-existent. However, the greenhouse use of Botanigard ES and Botanigard 22 WP warrants particular attention with respect to the use of beneficial insects in integrated pest management programs, particularly since the MPCA has demonstrated commercial relevance against various insect orders or families, including Homoptera (for example, whitefly, *Bemisia* spp., *Trialeurodes vaporarium*; aphid, *Myzuz persicae*, *Aphis gossypii*; leafhopper, *Erythoneura elegantula*), Thysanoptera (for example, thrips, *Frankliniella occidentalis*, *Thrips palmi*), Acrididae (for example, migratory grasshopper *Melanoplus sanguinipes*, North American grasshopper, African grasshopper, and locusts), and Lepidoptera (for example, Diamondback moth, *Plutella xylostella*, imported cabbage worm, *Pieris rapue*; cabbage looper, *Trichoplusia ni*). Non-target insect laboratory tests such as those submitted in the ecotoxicology package for *Beauveria bassiana* strain GHA reflect conservative measures of the potential for effects. Successful infection by *Beauveria bassiana* and spore germination requires suitable environmental conditions (for example, high moisture ca. 92–100%) which may or may not be reached in greenhouse settings. Other factors, such as behaviour of insects (for example, insect emergence, insect movement), seasonality, and habitat of insect species would further limit exposure, and thus mitigate risks to non-target insects. Nevertheless, based on the results from non-target insect testing and known

entomopathogenic nature of *Beauveria bassiana* strain GHA, it is reasonable to conclude that certain stages of particular insect species may be adversely affected in the event of direct exposure to Botanigard ES and Botanigard 22 WP under greenhouse conditions particularly when maximum application rates and repeat intervals are followed. Therefore, the labels will state that Botanigard ES and Botanigard 22 WP may be harmful to certain stages of particular beneficial insects. To reduce the risks to non-target insects, precautionary label statements will instruct users to minimize overspray in the greenhouse. Labelling will also advise users that Botanigard ES and Botanigard 22WP may be harmful to bees exposed by direct contact, and will instruct users to avoid applying the products to areas where honeybees are actively foraging.

7.3 Environmental Risk (Paragraph 4)

Although the non-target insect studies did not entirely meet guideline criteria, based on the low potential outdoor exposure of non-target terrestrial organisms, and on a weight of evidence from published and unpublished information, the use of Botanigard ES and Botanigard 22 WP is not expected to pose an unacceptable risk to non-target terrestrial organisms. Although the risk to the non-target insect species was found to be acceptable, in order to be protective of beneficial insects used commercially in greenhouses, the end-use product labels will state that Botanigard ES and Botanigard 22 WP may be harmful to certain stage of particular beneficial insects, and will instruct users to minimize overspray in the greenhouse. Labelling will also warn users that Botanigard ES and Botanigard 22WP may be harmful to bees exposed by direct contact, and instructs users to avoid applying the products to areas where honeybees are actively foraging. To reduce the potential for phytotoxic effects on crop plants, advisory statements notifying users to spot test plant surfaces before applying product and to minimize the accumulation of visible residues on plant surfaces, will also be required on the label under the directions for use section.

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B. Additional Information Considered

i) Published Information

1.0 Methods of Analysis

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PMRA Document Number: 1443979
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PMRA Document Number: 1536234
Reference: Goettel, M. S. And S. T. Jaronski. 1997. Safety And Registration Of Microbial Agents For Control Of Grasshoppers And Locusts. In: Memoirs Of The Entomological Society Of Canada. No. 171. Data Numbering Code: M2.0, M4.0, M9.0

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Reference: Zimmerman, G. 2007. Review On Safety Of The Entomopathogenic Fungi Beauveria bassiana And Beauveria brongniartii. Biocontrol Science And Technology. 17(5-6): 553-596. Data Numbering Code: M.2.7.2.

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Reference: Mel'nikova, E. A. And V. I. Murza 1980. Investigation Of The Safety Of Industrial Strains Of Microorganisms And Microbial Insecticides. Journal of Hygiene, Epidemiology, and Microbiological Immunity 24(4): 425-431. Data Numbering Code: M2.0, M4.0, M9.0

PMRA Document Number: 1593936
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